EUROPEAN COMMISSION

Brussels, 22.7.2010
C(2010)5217

COMMISSION DECISION

of 22.7.2010

on the transfer of the marketing authorisation granted by Decision C(2006)3721 for "Thelin - Sitaxentan sodium", a medicinal product for human use

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996[2] concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Article 6 thereof,

Having regard to the application submitted by Encysive (UK) Limited on 25 May 2010 under Article 3 of Regulation (EC) No 2141/96,

Whereas:

(1) The medicinal product "Thelin - Sitaxentan sodium", entered in the Community register of medicinal products under the number EU/1/06/353/001-005 and authorised by Commission Decision C(2006)3721 of 10 August 2006, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion,

(5) The marketing authorisation should be updated, and Decision C(2006)3721 amended accordingly.

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 286, 8.11.1996, p. 6.
3 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2006)3721 of 10 August 2006 to Encysive (UK) Limited for the medicinal product "Thelin - Sitaxentan sodium", entered in the Community register of medicinal products under No(s) EU/1/06/353/001-005, is transferred to PFIZER Limited.

Article 2

Decision C(2006)3721 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III B to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) The operations resulting from the transfer shall be implemented at the date of notification of this Decision.

Article 4

This Decision is addressed to:
1. PFIZER Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom
and
2. Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, on 22.7.2010.

For the Commission
Paola TESTORI COGGI
Director-General